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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/614,382	07/07/2003	Christopher J. M. Meade	1/1365	7418
28501	7590	11/17/2004		
BOEHRINGER INGELHEIM CORPORATION 900 RIDGEBURY ROAD P. O. BOX 368 RIDGEFIELD, CT 06877				
			EXAMINER SPIVACK, PHYLLIS G	
			ART UNIT 1614	PAPER NUMBER

DATE MAILED: 11/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/614,382

Applicant(s)

MEADE ET AL.

Examiner

Phyllis G. Spivack

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 August 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 2, 4-45 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 4-45 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

Applicants' Reply filed August 30, 2004 is acknowledged. Upon reconsideration the Restriction Requirement previously set forth is withdrawn. The claims are examined in their entirety. Claims 1, 2 and 4-45 are pending.

Information Disclosure Statements filed October 9, 2003, April 26, 2004 and August 30, 2004 are acknowledged and have been reviewed.

The abstract of the disclosure is objected to because it is not specifically directed to the present claims. Correction is required. See MPEP § 608.01(b).

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 2, 4-12 and 45 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-19 of copending Application No. 10/395501; claims 1-13, 15-25 of copending S.N. 10/391735; and claims 1, 2, 5-12 of copending S.N. 10/360064. Although the conflicting claims are not identical, they are not patentably distinct from each other because of overlapping subject matter. Steroids are well established medicaments in the treatment of

inflammatory diseases of the respiratory tract. The open language of the claims allows for the inclusion of additional active agents.

These are provisional obviousness-type double patenting rejections because the conflicting claims have not in fact been patented.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 2 and 4-45 are rejected under 35 U.S.C. 103(a) as being unpatentable over both Meissner et al., U.S. Patent 6,706,726, and Himmelsbach et al., U.S. Patent 6,656,946.

Meissner teaches the administration of the anticholinergics of formula I for use in the treatment of asthma and COPD. See, for example, Example 1, column 10. Meissner further teaches the optional co-administration with other active substances, and thus provides motivation to combine a compound of formula 1 with another compound that is effective when treating asthma or COPD. See column 22, lines 15-32, where inhalation is stated to be of particular importance. Himmelsbach teaches the administration of aminoquinazolines that are Epidermal Growth Factor Receptor (EGFR) kinase inhibitors to treat diseases of the lungs and airways. See claim 6, as well as column 11, lines 51-57. Therefore, in view of the combined teachings of the references, one skilled in the pulmonology art would have been motivated to prepare a pharmaceutical composition comprising an anticholinergic of instant formula 1 with an

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aminoquinazoline EGFR inhibitor with a reasonable expectation of treating various inflammatory or obstructive diseases of the respiratory tract. It is generally *prima facie* obvious to use in combination two or more ingredients that have previously been used separately for the same purpose. In re Kerkhoven, 205 USPQ 1069 (CCPA).

Obviousness does not require absolute predictability but only the reasonable expectation of success. Specific statements in the references that would spell out the claimed invention are not necessary to show obviousness since questions of obviousness involve not only what references expressly teach, but also what they would collectively suggest to one of ordinary skill in the art. The selection of optimal physical and chemical properties of an inhalable dosage, such as excipients, particle size, dosage forms, propellants (and volumes thereof), auxiliary agents, pH, solvent system, antioxidants, preservatives, as well as an anticholinergic of instant formula 1 and an EGFR kinase inhibitor, are all parameters well within the purview of those skilled in the art of formulation chemistry through no more than routine experimentation.

No claim is allowed.

Any inquiry concerning this communication should be directed to Phyllis G. Spivack at telephone number 571-272-0585. The Examiner can usually be reached Monday through Friday from 9:30 to 6 PM.

If attempts to reach the Examiner by telephone are unsuccessful after one business day, Chris Low, the Examiner's supervisor, may be reached at 571-272-0951.

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Phyllis Spivack

Phyllis G. Spivack

Primary Examiner

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November 13, 2004

**PHYLLIS SPIVACK
PRIMARY EXAMINER**